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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,343	03/26/2004	William A. Cook	3433-492	1552

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Indianapolis, IN 46204-5137

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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01/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/811,343

Applicant(s)

COOK ET AL.

Examiner

Paul B. Prebilic

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/17/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Upon more careful review of the claims and the arguments forwarded in the September 18, 2007 response, the Examiner decided to give a new non-final Office action.

Information Disclosure Statement

The information disclosure statement filed August 17, 2007 was not considered because the form (PTO-892 form) had an incorrect serial number such that it appears to be a copy of a PTO-892 form from another application. Moreover, it contains no clear location to place examiner initials or a signature and date.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claims 50-54, the language of claim 50 reciting that the peroxy compound is a peracid is confusing and contradictory. In other words, it should be one or the other. For this reason the claim language is considered to be indefinite. Claims 51-54 depend from claim 50 so they are indefinite by incorporating the language thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Badylak et al (US 4,902,508). Badylak anticipates the claim language where the order of the method steps is not fixed such that the removing step can be performed before the providing step. The tissue source as claimed is met by the autograft; see column 3, line 21 et seq. The disinfectant agent/treatment as claimed is the neomycin treatment (see column 4, lines 17-34), and the removing step as claimed is described on column 3, lines 53-62 of Badylak.

Claims 45-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Badylak et al (US 5,695,998). Badylak anticipates the claim language where the order of the steps as claimed is not fixed as explained in the previous rejection; see column 3, lines 3-44 of Badylak ('998).

With regard to claim 46, Applicants are directed to see column 8, lines 28-30.

With regard to claims 48-49, Applicants are directed to see Table 1 on column 8 where hydrogen peroxide is the oxidizing agent or peroxy compound. Acetyl peroxide is the organic peroxy compound of claim 51.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak et al (US 5,695,998) in view of O'Leary (US 5,298,222) or Kemp (US 5,460,962). Badylak discloses a submucosal tissue source which is first delaminated into tunica muscularis and tunica mucosa (i.e. submucosal tissue) prior to being disinfected; see column 3, lines 3-44. The present claim language requires a step of separation after the disinfectant treatment rather than before as Badylak discloses. However, O'Leary (see columns 1 and 2) or Kemp (see column 3, lines 21 et seq.) teaches that it was known to sterilize similar tissues prior to further mechanical processing. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to disinfect the submucosal tissue source of Badylak prior to delamination for the same reason that O'Leary does the same; see column 1, lines 34-39.

With regard to claims 28 and 29, Applicants are directed to see column 1, lines 41-59 of Badylak.

With regard to claim 30, Applicants are directed to see column 8, lines 28-30 of Badylak.

With regard to claim 37, Applicants are directed to see column 7, lines 55-64.

With regard to claims 31-33, Applicants are directed to see Table 1 on column 8 where hydrogen peroxide is the oxidizing agent or peroxy compound. Acetyl peroxide is the organic peroxy compound of claim 33.

With regard to claim 42 and 43, the solutions set forth in Example 2 of Badylak should inherently have the same pH as the claimed solution because they are the same as the claimed solutions. Alternatively, the Examiner asserts that the pH is Badylak is within the claimed range; see MPEP 2112 which is incorporated herein by reference.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

With regard to the traversal of the Section 112 rejection, the Examiner was not persuaded. In particular, peracids are at least derivatives of peroxy not subcomponents thereof. It may be that the Applicant means peroxyacid in claim 50 instead of peroxy; see Hawley's Condensed Chemical Dictionary on pages 886 and 890 as cited in this Office action.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilio whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilio/
Paul Prebilio
Primary Examiner
Art Unit 3774